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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/743,244	CHACORNAC ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-9 and 11-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-9 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 10/15/07 is acknowledged.

Note: Claims 16-20 have "currently amended and/or original" status identifiers, however, claims 16-20 were withdrawn in the previous Non-Final Office Action of 07/16/07. Claims 16-20 will not be examined in this action, based on non-elected subject matter.

Applicant has overcome the following rejection(s): The 35 U.S.C. 112, 2nd paragraph rejection of claims 3-10, based on insufficient antecedent basis of the claims, and claim 3, based on recitation of an outside range has been withdrawn by virtue of the amendment to the claims.

Claims 1-3, 5, 7-9 and 11-20 are pending in this action. Claims 16-20 have previously been withdrawn. Claims 4, 6 and 10 have been cancelled. Claims 1-15 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatesh *et al.* (U.S. Patent No. 6,475,510).

The instant invention is drawn to a composition intended for the oral administration of active ingredients with unacceptable taste, which comprises from about 15 to about 30% of active ingredient mixed with from about 50% to about 85% of an ester of glycerol or of a fatty acid, both percentages being of the total weight of the mixture of the composition, to which a wax is optionally added, and to which a surfactant is added, and wherein the composition is prepared by a spray-cooling process which produces a particle size of less than 350 μm.

Venkatesh *et al.* ('510) teach a fast-dispersible tablet for oral administration containing an active ingredient, a waxy material and a sweetener and/or a taste-masking agent to reduce bitter tasting ingredients (see col. 3, line 14 – col. 4, line 5).

The intragranular mixture requires blending of components, which include one or more medicaments, a component which is a waxy material and a taste-masking agent such as the lipoproteins and phospholipids derived from soy lecithin (col. 4, line 10 – col. 5, line 30).

Suitable waxy materials include mono-, di- or tri- aliphatic esters of glycerol, preferably glycerol palmitostearate (Precirol®) (col. 5, lines 31-39).

Suitable taste-masking agents in the intragranular formulation include the lipoproteins and phospholipids derived from soy lecithin (col. 5, lines 40-44).

Pharmaceutically active ingredients are disclosed at column 6, lines 9-35. The medicament can be comprised in 1-60 parts by weight (col. 7, lines 44-45).

The waxy material is present at a level of from about 1% to about 30%. While this range is lower than Applicant's claimed range of about 60% to about 80%, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that suitable or effective amounts of glycerol and/or fatty acid can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

The waxy material, taste-masking agents and sweetener agents for use in the intragranular component may also be optionally used in the extragranular admixture (col. 6, lines 5-8).

Additional excipients, such as flavoring agents, disintegrants and lubricants such as stearic acid can also be added to the formulation (col. 6, line 43 – col. 7, line 53); (col. 8, lines 1-10).

The Examples at columns 9-14 demonstrate various tablet formulations comprising active ingredient, waxy materials such as Precirol®, phospholipids and excipients (see for instance, Examples 2-4).

While Venkatesh *et al.* do not explicitly teach a particle size of less than about 350 μm, it is noted that the claim language "which can produce a particle size of less than about 350 μm" imparts future-intended use language and thus, does not afford patentable weight to the claims. Moreover, no unexpected results accrue from the instantly claimed particle size. Effective particle sizes can be determined by one of ordinary skill in the art through the routine optimization process.

Venkatesh *et al.* explicitly teach an orally administered tablet formulation comprising a blended intragranular admixture of pharmaceutically active ingredient, waxy materials, sweetening agent and/or taste-masking agent, and surfactant. The formulations are used to mask the bitter taste of active ingredients. The reference teaches and recognizes tablet formulations comprising essentially the same components as that being claimed by Applicant. Thus, given the teachings of Venkatesh *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered and were found partially persuasive.

- **Rejection under 35 U.S.C. 112 – 2nd paragraph:**

Applicant argued, "Claim 1 has been amended by the insertion of the limitation "both percentages being of the total weight of the mixture of the composition."

Applicant's arguments have been considered and were found persuasive by virtue of the amendment to the claims. Accordingly the 112, 2nd paragraph rejection of claims 3-10 has been withdrawn.

Applicant argued, "Claims 1 and 3 have now been amended whereby claim 1 now recites an ester of glycerol range of from about 50% to about 85% while claim 3, which depends there from has now been amended to recite a glycerol ester range of 60% to about 80%. Claim 3 is now more narrower than claim 1 and has proper antecedent basis."

Applicant's arguments have been considered and were found persuasive by virtue of the amendment to the claims. Accordingly the 112, 2nd paragraph rejection of claim 3 has been withdrawn.

- **Rejection under 35 U.S.C. 103(a):**

Applicant argued, "A main advantage of the compositions of the present invention is that the esters of glycerol selected and their amounts not only taste mask the bitter or irritating olefactory characteristics of many bad tasting pharmaceutical actives, but the particular glycerol esters useful in the practice of the present invention also have a suitable pH-sensitivity profile that delays dispersion and release of the active principle only on a delayed basis at acid pH conditions as encountered in the stomach. The glycerol esters then, serve to delay the release of the active until it passes the olefactory sensory system and enters the stomach. Nothing like this is disclosed in the cited prior art. The use of these glycerol esters together with the small particle size of the pharmaceutical active/glycerol ester component result in the advantage of an effective masking of taste coupled with a lack of the sandy or bitter feeling of the composition normally affiliated with said pharmaceutical active in the mouth."

Applicant's arguments have been fully considered, but were not found persuasive. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006). In this instance, the fact that Applicant has recognized another advantage, distinct from the prior art, which

accrues from a particular component, namely, from the esters of glycerol, does not impart patentability to the claims. Moreover, Applicant's argument the "particular glycol esters have a suitable pH-sensitivity profile that delays dispersion and release of the active principle only on a delayed basis at acid pH conditions as encountered in the stomach' was not persuasive, since Applicant's arguments do not establish the scope of claims being presented. The claims are silent with regard to any reference or recitation of pH-sensitivity release profiles and/or release of active principle due to incorporation of the esters of glycerol. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., pH-sensitive release profiles and/or release of active principle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's argument that "The use of these glycerol esters together with the small particle size of the pharmaceutical active/glycerol ester component result in the advantage of an effective masking of taste coupled with a lack of the sandy or bitter feeling of the composition normally affiliated with said pharmaceutical active in the mouth" has been considered, but was not deemed persuasive. Applicants are basing patentability on the grounds of particular properties achieved, in part, by the glycerol esters instantly claimed. However, it is noted that a compound and its' properties are inseparable. The prior art teaches inclusion of the same component - glycerol esters and therefore, one of ordinary skill in the art would envision and expect that the particular benefits and advantages imparted by that particular component would also be the same or essentially similar. Furthermore, "[T]he discovery of a previously

unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Thus, Applicant's arguments were not rendered persuasive.

Applicant argued, "The Venkatesh patent does not teach or suggest the instant claimed particle size of less than 350 μm, nor does it teach the esters of glycerol or fatty acid as taste masking agents. The small particle size is an important inventive and functional feature since this removes the sandy or chalky feeling of the composition normally affiliated with said pharmaceutical active in the mouth."

These arguments were not persuasive. While the Venkatesh patent does not teach the claimed particle size of less than 350 μm, it remains the position of the Examiner that no unexpected results accrue from the instantly claimed particle size that would result in a *patentable* distinction over the explicit reference teachings. The determination of suitable particle sizes, based on the intended purpose, can be attained by the routine optimization process. The removal of sandy or chalky feeling, by itself, is not sufficient to impart patentability to the claims, since this is merely an inherent property of the claimed particle size.

Lastly, Applicant argued, "It cannot be said that there is anything evident in the patent that teaches the combination of elements recited in the claims of the present application that are the spray-dried and cooled using a two-fluid nozzle to ensure that the desired particle size is

obtained, i.e. a particle size less than 350 μm diameter as described above. Every formulation disclosed in the Venkatesh *et aL* '510 patent is a dry granulation mixture for compaction, milling or slugging as a tablet."

This argument was not deemed persuasive. As delineated above, no unexpected results have been observed as a result of the instant particle size claimed (less than 350 μm), which would result in a patentable distinction over the teachings of the Venkatesh patent. Furthermore, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For the reasons advanced above, Applicant's arguments were not found persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1615

December 19, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER